EXHIBIT 30

EXPERT REPORT OF ROBERT L. HILL

In re National Prescription Opiate Litigation MDL No. 2804
Track One

May 31, 2019

I. QUALIFICATIONS

1. My name is Robert L. Hill, and I am a retired government and pharmaceutical industry executive with over 25 years of experience as a Special Agent/Criminal Investigator with the United States Drug Enforcement Administration ("DEA"), which included over 14 years of management/executive positions. For the last six years of my career at DEA, I was assigned to the Office of Diversion Control at DEA Headquarters. From July 2012 to December 2014, when I retired, I served as the Executive Assistant to the Deputy Assistant Administrator, Office of Diversion Control. I am currently an independent consultant.

2. I earned a Bachelor of Science in Criminal Justice from Wayne State University in 1988.

3. I began my law enforcement career in August 1988 as a police officer in the City of Dearborn, Michigan. In September 1989, I became a DEA Special Agent in Detroit, Michigan. I conducted criminal and financial investigations against individuals and organizations that were suspected of violating the Controlled Substances Act ("CSA") and/or state narcotics statutes. From July 1996 to November 1998, I served as the Divisional Training Coordinator for DEA's Detroit Field Division, which covered Michigan, Ohio, and Kentucky.

4. In November 1998, I was reassigned to the Belize Country Office in Central America. I advised the U.S. Ambassador to Belize and the Belizean Government on counter-narcotics missions of the United States and Belize.

5. In April 2000, I returned to DEA's Detroit Field Division as a Group Supervisor for Enforcement Group III. I managed the day-to-day activities of twelve Special Agent/Criminal Investigators and two local police officers who were conducting criminal and financial investigations against individuals and organizations that were suspected of violating the CSA and/or state narcotics statutes. In addition, I assisted the Diversion Group in the Detroit Field Office, which is tasked with investigating registrants to ensure compliance with the CSA and its implementing regulations (Diversion Response Group).

6. In October 2005, I was reassigned to DEA Headquarters as a Staff Coordinator for the Latin America and Caribbean Section. There, I provided operational support and coordination to

assist foreign offices located in Latin America and the Caribbean in the development and furtherance of major drug and financial investigations.

7. In January 2009, I was promoted to Section Chief of the Pharmaceuticals Investigation Section. This section included the Targeting and Analysis Unit and the Pharmaceutical Investigations Unit. The Targeting and Analysis Unit reviewed Automation of Reports and Consolidated Orders System ("ARCOS") information and if it was deemed necessary leads would be sent out to the field for further investigation. The Pharmaceutical Investigations Unit would handle and/or assist investigations dealing with pharmaceutical controlled substances done in association with the field throughout the country.

8. In this role, I served as DEA's technical expert and provided programmatic oversight of enforcement strategies and operations aimed at stopping the diversion of pharmaceutical controlled substances. I also oversaw DEA's Tactical Diversion Squads Program, ARCOS, Drug Theft and Loss Database and Suspicious Orders Monitoring Program ("SOMP").

9. In July 2012, I was reassigned to be the Executive Assistant to the Deputy Assistant Administrator for the Office of Diversion Control. I assisted the Deputy Assistant Administrator with managing the day-to-day operations of the Office of Diversion Control. This included, but was not limited to: overseeing, coordinating and providing strategic direction to a DEA headquarters team of 300 personnel and 1,000 field personnel on all major regulatory, pharmaceutical, precursor chemical, clandestine laboratory and synthetic drug investigations; the issuance of administrative actions; the drafting and promulgating of regulations; establishing drug production quotas; preparing congressional testimony and briefing; conducting speaking engagements and media interviews; and serving as liaison to the pharmaceutical industry, international governments, state governments, federal agencies and law enforcement agencies. In December 2014, I retired from DEA.

10. From January 2015 until July 2018, I worked as the Director of DEA Compliance and Corporate Security for Amneal Pharmaceuticals. In this role, I ensured that all Amneal locations in Kentucky, New Jersey and New York that were authorized to handle controlled substances were in compliance with the Controlled Substances Act and its implementing regulations, as well as ensuring that appropriate security measures were in place to protect employees, facilities and

proprietary information. In my role, I also managed Amneal's Suspicious Order Monitoring Program.

11. My CV, which provides additional details about my professional experience, is attached as Appendix A. My billing rate is $675 per hour, and my compensation is not dependent on my opinions or the outcome of this litigation.

12. I have not testified as an expert at trial or by deposition in the last 4 years.

13. I have authored no publications in the last 10 years. However, I was part of the working group that led to the authoring of *The Prescription Opioid Epidemic: An Evidence-Based Approach*, Johns Hopkins Bloomberg School of Public Health (November 2015), https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

II. ASSIGNMENT

14. I have been retained by Zuckerman Spaeder LLP, on behalf of CVS Indiana, L.L.C. and CVS Rx Services, Inc. ("CVS") to serve as an expert witness in *County of Cuyahoga v. Purdue Pharma L.P.*, No. 17-OP-45004 and *County of Summit v. Purdue Pharma L.P.*, No. 18-OP-45090. I understand that Summit and Cuyahoga counties have sued CVS and that they allege that "various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market."[1] CVS Indiana, L.L.C. operates an Indianapolis, Indiana distribution center and CVS Rx Services, Inc. operates a Chemung, New York distribution center, and both are licensed to distribute Schedule III-V controlled substances in Ohio.[2] I understand that neither company is sued for dispensing (filling prescriptions).[3]

15. I have relied on my professional experience and considered a number of depositions and documents produced in this case in forming my opinions. A list of the materials I considered is attached as Appendix B. I also considered information provided in conversations with CVS employees identified in this report.

[1] Second Corrected Amended Complaint, *County of Summit, Ohio v. Purdue Pharma L.P.*, No. 18-OP-45090 (N.D. Ohio), ECF No. 514, ¶ 9.

[2] CVS Indiana L.L.C. (Indianapolis, Indiana), License No. 011648300, Board of Pharmacy, Wholesaler – Category 3, eLicense Ohio, https://elicense.ohio.gov/oh_verifylicensedetails?pid=a0Rt0000000rvcuEAA; CVS Pharmacy Distribution Center (Chemung, NY), License No. 012395150, Board of Pharmacy, Wholesaler - Category 3, eLicense Ohio, https://elicense.ohio.gov/oh_verifylicensedetails?pid=a0Rt0000001EL1XEAW.

[3] Opinion and Order on Motions to Dismiss, *County of Summit. v. Purdue Pharma L.P.*, No. 18-OP-45090 (Dec. 19, 2018 N.D. Ohio), ECF No. 1203, p. 2 ("The Court understands that Plaintiffs have disclaimed any cause of action against Retail Pharmacies in their capacity as retailers or dispensers of opioids[.]").

administrative actions if it has serious concerns with a registrant's compliance with DEA regulations. The fact DEA not only waited more than 28 months before issuing the LOA, but that it also issued it on the last day of the year in 2015 shows that a DEA official issued the LOA for statistical reasons. Additionally, in 2013, DEA would have taken an administrative action more severe than an LOA if it believed a distribution center was failing to detect suspicious orders. As stated above, an LOA is the least serious administrative action available to DEA.

b. Chemung Distribution Center

37. CVS's Chemung, New York distribution center opened in 2011.[38] It operates as CVS Rx Services, Inc., d/b/a CVS Pharmacy Distribution Center.[39] DEA conducted a pre-registration inspection in April 2011.[40] On June 28, 2011, DEA granted the Chemung distribution center a DEA certificate of registration to distribute Schedule III-V controlled substances.[41] DEA conducted a routine inspection of the Chemung distribution center on June 17th, 19th, and 20th, 2013.[42] Between 2011 and the present, on an annual basis, DEA has renewed Chemung's certification of registration.[43] DEA has taken no administrative action against the Chemung distribution center.[44]

2. CVS Controls

a. 2006-2009

38. From 2006 to 2009, CVS had several controls in place relating to its distribution of controlled substances.

[38] Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[39] Chemung DEA Registration Certificates: CVS-MDLT1-000127091; CVS-MDLT1-000000117; CVS-MDLT1-000000102; CVS-MDLT1-000000088; CVS-MDLT1-000000077; CVS-MDLT1-000127090; Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[40] CVS-MDLT1-000123069 (CVS Official Government Agency Visits).

[41] CVS-MDLT1-000023148 (June 28, 2011 DEA Registration Certificate).

[42] CVS-MDLT1-000123069 (CVS Official Government Agency Visits).

[43] Chemung DEA Registration Certificates: CVS-MDLT1-000127091; CVS-MDLT1-000000117; CVS-MDLT1-000000102; CVS-MDLT1-000000088; CVS-MDLT1-000000077; CVS-MDLT1-000127090; Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

[44] Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

39. First, CVS distributed only to CVS pharmacies.[45] It did not distribute to known sources of diversion, such as rogue pain clinics, rogue internet pharmacies, or dispensing practitioners.

40. Second, CVS did not distribute Schedule II controlled substances.[46] It did not therefore distribute controlled substances such as fentanyl, hydromorphone, oxycodone, or oxymorphone, which had the highest potential for abuse of any prescription drugs.[47] It distributed only Schedule III-V controlled substances, and it voluntarily stopped distributing hydrocodone combination products, which were Schedule III controlled substances, when DEA reclassified them to Schedule II in October 2014.[48]

41. Third, the Indianapolis distribution center, the only CVS defendant which distributed Schedule III-V controlled substances to pharmacies in Summit and Cuyahoga counties during this time period, had a manual system for reviewing orders of controlled substances. Employees who picked and packed or checked those orders were responsible for bringing any potentially unusual orders to the attention of their supervisors. Ellen Wilson, who picked and packed orders in the controlled substances cage for over twenty years at the CVS Indiana distribution center, testified that she used her years of experience and her "gut feeling" to bring unusual orders to her supervisor's attention.[49] Each order was reviewed not only by a picker but also by a checker, so

[45] Deposition of Mark Vernazza, p. 56:10-13 (the two CVS defendants "only distributed controlled substances to CVS pharmacies, to the best of my corporate knowledge."); Expert Report of Sonya Kwon, pp. 7-9.

[46] Deposition of Mark Vernazza, p. 56:2-9 ("Both of the CVS entities named as defendants in this case are distributors of controlled substances. They are now, and have always been, only distributors of Schedule III through V controlled substances, and have never been distributors of Schedule II controlled substances."); Expert Report of Sonya Kwon, pp. 9-11.

[47] 21 U.S.C. § 812(b)(2) (defining Schedule II controlled substances as having "a high potential for abuse" and "a currently accepted medical use[.]").

[48] Expert Report of Sonya Kwon, p. 9-11.

[49] Deposition of Ellen Wilson, pp. 61:8-62:19; Deposition of Mark Nicastro, pp. 298:5-12; 300:18-22 ("They would -- they would go through and pick the orders and they would review the orders for anything of unusual size. These were our experts. They were in the cage every single day. They picked these orders every single day. And they are going to be the best -- have the most knowledge as to whether an order seems unusual size or pattern . . . We relied on them to use their experience to flag anything that looked suspicious to them, and they would -- they would escalate those to their pharmacy supervisor or manager, and they would take it from there."); Deposition of Gary Millikan, pp. 132:25-133:6 ("When you're there [as a picker and packer] and you're doing it, something just doesn't feel right sometimes. For example, you go to this one section and you -- in that number of stores you're picking today, you pick one and one and one and one, and you get an eight. Does eight concern you? Bring it up to us. Let's look into it.").

two persons in the controlled substances cage independently reviewed every order.[50] It was CVS policy to decline to ship any order, which was determined to be suspicious, and to report the order to DEA.[51] In my opinion, a manual system of this nature meets the requirements of 21 C.F.R. § 1301.74(b) and was reasonable.[52]

42. Fourth, CVS had in place a program through its pharmacy loss prevention department to monitor ordering patterns, among other things. The program was based on a monthly report called the Prescription Drug Monitoring Report ("PDMR"). This report was reviewed by personnel in the field called Regional Loss Prevention Managers ("RLPMs"), each of whom had responsibility for a particular geographic area. There were several RLPMs for the Cleveland and Akron areas. For pharmacies that were identified for review by a computerized system, based on the following information, the PDMR showed for the pharmacy the particular drug in question, the drug schedule, the number of dosage units received from CVS distribution centers, the number of dosage units received from any outside vendor, the number of dosage units dispensed, the difference between the dosage units received and the dosage units dispensed, any difference between expected inventory and the manual inventory reported by the pharmacy, and any manual changes made by the pharmacy to increase the size of the computer-generated order.

43. This information enabled RLPMs to identify potential concerns requiring further investigation relating to ordering patterns or possible diversion. The RLPMs would then conduct investigations as they saw fit, and to the extent they identified concerns they would address them in conjunction with the pharmacy manager (pharmacist in charge). Although the PDMRs were generated monthly and could not have been used to identify suspicious orders in real-time, they complimented the real-time suspicious order monitoring program by providing for a monthly

[50] Conversation with Ellen Wilson, Warehouse Employee, Indianapolis Distribution Center; Conversation with Gary Millikan, Retired Operations Manager, Indianapolis Distribution Center.

[51] "When CVS determines that an order for a controlled substance is suspicious, its policy is and has been to decline to ship the order and to report the order to the DEA." CVS's Written Responses to Topics 8, 9, 12, 13, and 14 of Plaintiffs' Amended Second Notice of Deposition Pursuant to Rule 30(b)(6) (Nov. 15, 2018) ¶ 14.

[52] Mr. Rafalski and Mr. Whitelaw criticize Ms. Wilson for relying on her "gut" instincts. Expert Report of James Rafalski, p. 105; Expert Report Seth Whitelaw, pp. 169-170. It is very reasonable for a warehouse employee to rely on her gut based on her knowledge and experience.

review of ordering patterns and by addressing circumstances of concern.[53] This was another effective control against diversion and another form of due diligence.

44. While the above controls are sufficient in and of themselves, I note that CVS's pharmacy business also had in place policies on the proper dispensing of controlled substances and assigned pharmacy supervisors to each pharmacy to promote conduct at the pharmacies consistent with the policies. Its policies stated that "[e]mployees are expected to fill and refill only legal and authorized prescriptions" and that "[t]he exercising of corresponding responsibility is especially important with regard to 'questionable' prescriptions for controlled drugs."[54] Pharmacy supervisors, who supervised pharmacy managers, were not on staff at a pharmacy and rather were assigned to oversee several pharmacies in a particular geographic area, were present in each pharmacy they supervised typically at least once a month (or more often as needed). Their job was to work with the pharmacists on overall compliance, patient needs, and pharmacy operations. This was in addition to the pharmacy manager (pharmacist in charge) in each of the pharmacies and to the RLPMs who also monitored the pharmacies.[55]

b. 2009 – Early 2014

45. From 2009 to early 2014, CVS kept in place the above controls related to its distribution of controlled substances and enhanced them by adding a computerized system to assist in identifying potentially suspicious orders and a process for manually reviewing the reports from that system. In the spring of 2008, CVS hired an outside consultant, Ronald Buzzeo, former

[53] Conversation with John Robinson, Director of Asset Protection; CVS-MDLT1-000068377 (May 29, 2007 PDMR Report).

[54] CVS-MDLT1-000055540 (December 21, 2004 Professional Practices Policy); CVS-MDLT1-000081559 (June 30, 2011 Suspected Fraudulent or Altered Prescriptions Policy) ("Employees should be constantly [on] alert for any potential indicators of diversion, including the use of fraudulent or altered prescriptions to obtain medications . . . If a pharmacist has a question about any aspect of a prescription, the pharmacist must not dispense until the legitimacy can be verified."); CVS-MDLT1-000081566 (January 4, 2012 Protocol for Dispensing Narcotic Drugs for Pain Treatment) (Pharmacists "should exercise particular caution before filling a prescription . . . from practitioners who prescribe the same medication in the same dosage amounts to most or all of their patients . . . from practitioners who you are aware do not take insurance or whose patients have insurance but always insist on paying cash for their prescriptions. . . from individuals who come to the pharmacy in groups to get narcotic prescriptions filled."); CVS-MDLT1-000081508 (February 22, 2012 Professional Standards Policy) ("Employees are expected to fill and refill only legal and authorized prescriptions. They are expected to uphold this legal and moral responsibility by keeping up to date on all State and Federal changes in pharmacy jurisprudence[.]").

[55] Deposition of Mark Vernazza, pp. 146:10-148:4; Conversation with Nicole Harrington, Senior Director of Pharmacy Services.

Deputy Director of DEA's Office of Diversion Control, and his company to design this computerized system.[56] Mr. Buzzeo was a very reasonable choice for this work. Mr. Buzzeo's company delivered the computerized SOM system in December 2008.[57]

46. The Buzzeo computerized system was put in place in the first part of 2009.[58] The system was based on an algorithm that relied on historical information and scored each order.[59] If a score exceeded a certain level, the order would appear on a daily item review report ("IRR") for a CVS analyst to review.[60] The system did not identify suspicious orders. Rather, it identified orders that "should be 'pended' to allow further investigation to determine whether the order is in fact a 'suspicious order' for reporting purposes."[61] In my opinion, this system complied with 21 C.F.R. § 1301.74(b) and was reasonable.[62]

47. The IRR identified information such as the drug ordered, the size of the order, the store that ordered it and information about order history.[63] Each item on the report was reviewed by CVS analysts.[64] The analysts testified that they understood the IRR at the time they reviewed it.[65] Reviewing the IRR in and of itself was a form of due diligence.[66]

---

[56] CVS-MDLT1-000119208 (2008 Consulting Services Agreement) (CVS hired Mr. Buzzeo and his company to "customize a suspicious order monitor (SOM) statistical model for [CVS] using [Buzzeo's] Ph.D. statisticians and DEA consulting team.").

[57] CVS-MDLT1-000123386 (December 2008 Overview of Buzzeo SOM Model); CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[58] CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[59] CVS-MDLT1-000123386 (December 2008 Overview of Buzzeo SOM Model); CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[60] Deposition of Aaron Burtner, pp. 69:20-70:5 ("Q. Okay. And that Item Review Report was a result of the computer system going through its algorithm process to then cause certain orders to appear on that IRR report daily. Is that right? . . . A. That is my understanding."); Deposition of John Mortelliti, p. 40:7-9 ("Q. In addition to an IRR -- and this is a daily report, right? A. Yes.").

[61] CVS-MDLT1-000034192 (2011 Buzzeo Retunement).

[62] Dr. William Choi evaluated this system and determined that it was based on reasonable statistical methods. Expert Report of William Choi, pp. 3, 12.

[63] CVS-MDLT1-000010672 (August 30, 2013 IRR); Deposition of Aaron Burtner, p. 122:2-8 ("Q. And the [IRR] report identifies orders that are statistically significant or that vary from historical monthly trends based upon the previous six months as well as the current month. Correct? A. Yes.").

[64] Deposition of Aaron Burtner, pp. 521:20-522:3 ("To the best of your knowledge, did you and the SOM team, when you worked in SOM, review all of the orders flagged on an IRR . . . Q. -- on a daily basis? A. Yes. We reviewed every order on the IRR on a daily basis."); Deposition of Shauna Helfrich, p. 245:18-20. ("Q. Do you remember whether you reviewed all of the orders that CVS's system flagged? A. Yes."); Deposition of John

48. The analysts had the ability to conduct additional due diligence beyond the IRR, if they believed it was necessary, to come to a reasonable conclusion about whether the order was suspicious or not. They had access to other CVS resources, including loss prevention personnel, pharmacists from the store that placed the order[67], and other databases with pertinent information i.e. VIPER[68] and Microstrategy.[69] The analysts testified that they had the time and resources necessary to conduct their due diligence.[70]

Mortelliti, p. 54:6-17 ("What do you do with the hydrocodones that are flagged as of interest or potentially suspicious? A. Freeze the orders within the distribution centers. I would contact the field VIPER analyst in those areas. I would also contact the regional loss prevention managers for them to do an investigation. Q. And you did that in 2009 up to October of 2010 for every flagged hydrocodone order. Is that your testimony? A. Yes."); Deposition of Mark Vernazza, pp. 394:21-395:4 ("Q. And the IRR report is what's being reviewed every day to look for flagged orders so you can start to investigate, correct? . . . A. That's my understanding.").

[65] Deposition of Aaron Burtner, pp. 522:18-523:5 ("And during that same -- at that time, you also understood the information presented in the IRR? . . . Yes, at that time I understood the IRR Q. Including all the scores that appeared for each drug in the IRR? . . . A. Yes. I had a much better understanding of all of the data on the IRR at that time."); Deposition of Shauna Helfrich, p. 245:8-11. ("Q. Ms. Helfrich, do you recall whether at the time you were a SOM analyst you felt you understood the IRR? A. Yes.").

[66] Other than section 21 C.F.R. § 1301.74(a), the CSA and its implementing regulations do not dictate how to conduct due diligence. CVS satisfies the requirement in § 1301.74(a), through its internal mainframe, which only allows orders from pharmacies with active DEA registrations. Conversation with Linda Cimbron, Director of Licensing; Conversation with John Andrade, Senior Manager, Application Development, IS - Retail Systems-Logistics.

[67] Deposition of Shauna Helfrich, pp. 196:1-6 ("Q. Can we talk generically about what due diligence can be done to figure out whether or not a order is suspicious? So you can contact and speak to the pharmacist, correct? A. Yes.")

[68] VIPER, which was available throughout the Buzzeo era, provided information about the store's ordering history. Deposition of Kelly Baker, p. 136:4-8 (VIPER "lets you compare how many was shipped versus how many was dispensed[.]"); Deposition of Shauna Helfrich, p. 29:6-8 ("The Viper Report, as I can remember, gave me the balance on hand for that store for a particular drug[.]"); Deposition of Aaron Burtner, p. 380:12-15 ("Q. What this [VIPER PDMR] tells you is how much was shipped to the pharmacy and how much was dispensed from the pharmacy, correct? A. Correct.").

[69] Microstrategy, which became available to the analysts later, provided information about the pharmacy's dispensing. Deposition of Aaron Burtner, p. 380:7-12 (MicroStrategy had "dispensing history for a store and several data points related to the script that was filled, such as doctor, customer, payment method, how far the customer had driven from their home to the location[.]"); Deposition of Shauna Helfrich, p. 19:3-6 (Microstrategy had "the patient ID number, doctors, and PI number. Insurance, how the drug was paid for [and] [q]uantity of the drugs, dispense[d].").

[70] Deposition of Shauna Helfrich, p. 246:4-7 ("Q. When you were a SOM analyst, did you always conduct the due diligence that you believed was necessary? A. Yes."); Deposition of Kelly Baker, pp. 366:24-367:4 ("Q. Was there ever a time when you felt you did not have the resources or time to complete your job? A. That's kind of -- I think we had the resources I needed to do my job."); Deposition of Aaron Burtner, p. 522:12-16 (Q. And did you have access to all of the data and information that you thought was necessary to evaluate those orders? . . . A. Yes, I believe so.").

49. Notably, in August 2013, CVS hired Matthew C. Murphy, DEA's former head of Pharmaceutical Investigations and his company the Pharma Compliance Group, to assist its analysts with their suspicious order monitoring due diligence. Pharma Compliance continued to assist until early 2014.[71]

50. It was CVS policy not to ship an order listed on the IRR until or unless it was cleared and to report any suspicious orders, when discovered, to the DEA.[72] The SOM analysts testified that they were not aware of any suspicious orders that shipped.[73]

51. In March 2012, when this system was in operation, CVS "[a]s part of [its] efforts to continuously assess and enhance its controlled substances and listed chemical systems and processes . . . requested the assistance of the Drug and Chemical Advisory Group, LLC. (DCAG) in conducting an evaluation of its suspicious order monitoring (SOM) program[.]"[74] The evaluation was conducted by Terrance Woodworth. Mr. Woodworth was the former Deputy Director, DEA Office of Diversion Control.

52. As part of his evaluation, Mr. Woodworth spent three days at the distribution center where the SOM system was being managed, and he met with among others, two SOM analysts conducting the daily IRR review.[75] Mr. Woodworth concluded that CVS "has established an effective, centrally operated suspicious order monitoring program . . . and CVS continues to update and improve its SOM program."[76] He also concluded "that the overall approach is not focused on reviewing and rapidly releasing an order to ensure store delivery dates. The priority

[71] CVS-MDLT1-000104918 (August 2013 Pharma Compliance Group Engagement Letter); Deposition of Dean Vanelli, p. 235:16-238:6; Deposition of Kelly Baker, pp. 59:1-60:13; Deposition of Shauna Helfrich, p. 224:4-21.

[72] CVS-MDLT1-000109871 (February 29, 2012 Work Instruction Loss Prevention Analyst); CVS-MDLT1-000009812 (March 28, 2012 List 1 Chemicals (PSE, EPH) and Control Drug Policy & Procedure).

[73] Deposition of Shauna Helfrich, p. 248:9-11 ("Q. Did you ever let an order ship that you were concerned might be suspicious? A. No."); Deposition of Aaron Burtner, p. 523:20-24 ("Q. Okay. But you're not aware of any suspicious order that CVS shipped during your time working in SOM for CVS? . . . A. No, I am not.").

[74] CVS-MDLT1-000125136 (April 6, 2012 DCAG Report).

[75] CVS-MDLT1-000125136 (He "met with several key members of the CVS SOM team: Frank R. Devlin, Director Logistics Loss Prevention (Rhode Island), John Mortelliti, Logistics Regional Director, Loss Prevention (New Jersey), Pamela J. Hinkle, Senior Loss Prevention Manager, (Tennessee), Paul Lawson, Logistics Loss Prevention Analyst (Tennessee), Aaron J. Burtner, Logistics Loss Prevention Analyst (Indiana), Attorney Margaret P. Griffiths, (Illinois), and King & Spaulding Attorney Stephen P. Cummings (Georgia).").

[76] CVS-MDLT1-000125136 (April 6, 2012 DCAG Report).

clearly is to detect any problem or issue that indicates an order may not be valid or legitimate. The review and analysis of irregular orders are completed expeditiously; and while sales productivity, customer store and patient satisfaction are paramount, the foundation of the CVS SOM is ensuring the legitimacy of these transactions."[77]

53. This system was designed, evaluated, or assisted by three former high-ranking DEA officials from the Office of Diversion Control.[78] The selection of these individuals shows CVS's commitment to its suspicious order monitoring program.

c. Early 2014 – End of 2014

54. In early 2014, CVS replaced the Buzzeo system with a new computerized system to assist in identifying potentially suspicious orders. Like the Buzzeo system, this system operated in conjunction with controls discussed above in Section V.E.2.a. Even though this system has been in operation continuously through the present, CVS stopped distributing HCPs after September 2014. I travelled to CVS corporate headquarters in Woonsocket, Rhode Island to see the system in operation. While there, I sat with one of the analysts (Megan Matos) and the group supervisor (Annette Lamoureux) and observed their work in real-time.

55. The new system is based on a set of computerized tests that identifies orders for review. Some of the tests are based on size, some are based on frequency, and some are based on ordering pattern. The tests are run overnight against every order placed by a CVS pharmacy the preceding day, and the system identifies orders for review based on one or more of the tests. Every order that is identified is then held and placed in a queue for review.

56. Beginning in the early morning, CVS analysts begin their reviews by selecting an order from the queue. The analyst opens a file, which shows basic information about the order for review, such as the drug that was ordered, how much was ordered, the pharmacy it was ordered from, and the distribution center that would fill the order. The computer interface allows the analyst to link to more specific information. For example, the analyst can see information

[77] CVS-MDLT1-000125136 (April 6, 2012 DCAG Report).

[78] This system covered all of the CVS distribution centers that were registered to distribute Schedule III-V controlled substances. Other than the 2015 LOA issued to the Indianapolis distribution center discussed above, DEA never took any action against CVS based on this system. CVS-MDLT1-000123069 (CVS Official Government Agency Visits); Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

related to the relevant tests, the pharmacy, the order, the patient, the prescriber, cocktail information, and the method of payment. The analyst can supplement his or her review through additional information, such as a map showing what is in the vicinity of the pharmacy, a comparison of the amount of the drug ordered and the amount dispensed, the balance on hand for the particular drug at the pharmacy, and the distance the patient travelled. All of this information is accessible through each analyst's computer. When deemed necessary, an analyst may also call the pharmacy to ask any questions raised by his or her review.

57. Based on an analyst's review of this information, the analyst decides whether to clear the order or not. If the analyst is unable to resolve any questions about the order, the order continues to be held and is elevated for further review. The order is then either: (1) cleared as not suspicious; or (2) identified as suspicious, not shipped and reported to DEA.

58. In my opinion, this system complied with 21 C.F.R. § 1301.74(b) and was reasonable.

F. It is Reasonable that CVS Did Not Discover Any Suspicious Orders Placed by Pharmacies in Summit and Cuyahoga Counties.

59. DEA regulations require a system to disclose and report, when discovered, suspicious orders. However, this does not mean a customer will place a suspicious order.[79] If no suspicious orders are placed, there are none for the distributor to discover or report. Based on the circumstances here, it is reasonable in my opinion that CVS did not discover any suspicious orders placed by any of the CVS pharmacies in Cuyahoga and Summit counties and therefore did not report any.

60. First, CVS distributed only to CVS pharmacies.[80] It did not distribute to known sources of diversion, such as rogue pain clinics, rogue internet pharmacies, or dispensing practitioners. CVS therefore did not receive orders from these types of customers.

61. Second, CVS did not distribute any of the controlled substances that were considered to have the highest potential for abuse of any prescription drugs (Schedule II).[81] It did not

[79] 21 C.F.R. § 1301.74(b).

[80] Deposition of Mark Vernazza. p. 56:10-13 (the two CVS defendants "only distributed controlled substances to CVS pharmacies, to the best of my corporate knowledge."); Expert Report of Sonya Kwon, pp. 7-9.